

R E M A R K S

Claims 2 to 47, 49, 50, 116 to 125 are pending in the present application.
Claims 2, 49 and 116 are independent.

Section 103 Rejections

Claims 2 to 47, 49, 50, 116 to 125 stand rejected under 35 U.S.C. Section 103(a) as being unpatentable over various combinations of Reber (5,950,632) and Huerga (5,852,590) (Claims 2 to 5, 18 to 23, 25 to 31, 36 to 38, 43 to 47, 49, 50, 116 to 118, 121, 125) in view of Official Notice (Claims 24, 39, 40, 122 to 124), Mauney (6,484,027) (Claims 6 to 8, 41, 42, 119, 120), McEwan (5,589,839) (Claims 9 to 17), and McIntosh (4,682,299) (Claims 32 to 35).

Regarding all of the claims rejected under Section 103, Applicants assert that the Examiner has not met his burden of establishing a *prima facie* case of obviousness in that the Huerga reference does not disclose that for which the Examiner relies upon it. Despite the Examiner's assertions to the contrary, Huerga does not teach "wirelessly communicating a signal between the first container and a second container" (or the like) as recited in each of Applicants' pending independent claims. Huerga has absolutely no disclosure at all regarding communication between medicine containers. The passages that the Examiner relies upon merely state:

This invention relates to a multi-piece, automated medication container having a first piece with an interactive label and a machine readable and writable electronic memory strip. The memory strip contains prescription information, medication information and program codes that are downloaded to a second piece having a computer processor. In one embodiment of the invention, the interactive label is affixed to a vial of a standard childproof container. The vial is sealed by an automated cap. The automated cap includes sensors for reading the information and codes on the memory strip and a memory for storing the information and codes. The automated cap also includes a display for visually or audibly indicating desired information to the patient, such as when to take the next dose of medication. A computer controlled locking assembly in the cap presents its removal before the prescribed time for taking the next dose of medication. The sensors also obtain actual medication consumption information based on when the container is opened. This actual consumption information is used to keep inventory information regarding the number of doses remaining in the container. The actual consumption information and inventory information is stored in the memory of the cap or sent to the interactive label to update the memory strip. The memory strip can also contain contraindication information for downloading to a personal home computer or a hospital or nursing home computer. In an other embodiment, the interactive label is affixed to a blister pack containing individual doses of medication. The blister pack is then placed in an automated dispenser. (ABSTRACT)

As stated above, the information 80 contained in the memory strip 60 can be transmitted to a separate personal or business computer 270 or personal alerting device 290, such as a digital watch or appointment book, by equipping automated cap 100 with an infrared transmitter 140. The transmission is started by pressing button 160 for several seconds. The transferred information is used to establish an alert timing schedule 82 to remind the patient when to take the medication 15. This is accomplished by having the computer 270 activate a variety of its alarms, or by having the computer page the patient with a message to consume a specific medication, or by calling the patient using a telephone to convey a verbal message to consume a specific medication. In this manner, the patient can extend the alarm and alerting devices beyond what is available in the cap 100, or to have alerts be issued even if a conventional cap is used.

If a patient is taking several medications 15 and the information 80 contained in the memory strip 60 for each container 10 is transferred to a separate personal or business computer 270, the computer can reference and compare the lists of contraindicated medications which are part of the medication information 84. Should two or more medications 15 be contraindicated for use together, the patient will be alerted to this fact. Every time a medication 15 is issued to a patient, the most recent list of contraindications is included in the

memory strip 60 of the container 10. If the patient does not have a software program capable of performing this function, the program codes 86 will contain a program that is transferred from the memory strip 60 to the computer 270 to perform this check. This program may use a Java programming language so that it can be used in a wide variety of computer processors 270. Other program codes 86 can be sent to the automated cap 100 or computer 270 to perform various alerting functions. (COL. 13, LN. 57 to COL. 14, LN. 24)

As shown in FIG. 9, the automated cap 100 includes a computer processor 120 having its own memory 125. The processor 120 and memory 125 are located on and in electrical communication with a circuit board 130 located inside the cap 100 for protection. (See FIG. 4.) The circuit board 130 electrically connects the processor 120 to a visual communication device such as an LCD display 132. The LCD display 132 visually displays desired information to the patient, such as the date and time the next dose of medication is to be taken and the number of pills to be taken. The display 132 can also indicate an alert or warning to the patient, such as the fact that the patient is so overdue in taking a dose of medication that that dose should no longer be taken. The circuit board 130 also electrically connects the processor 120 to a variety of alarming devices such as audible, visual and vibrational communication devices or alarms 134, 136 and 138, respectively. These alarms 134, 136 and 138 indicate a variety of warnings to a patient, such as when it is time to take a dose of medication. The circuit board 130 also electrically connects the processor 120 to a communication device such as an infrared transmitter 140 that transmits information to or receives information from a separate personal or business computer 270 as discussed below. (COL. 11, LNS. 35 to 58)

A further advantage of the present invention is that the memory strip can contain prescription requirements that include instructions for alternating between differing medications in a controlled sequence. For example, some advances in Acquired Immune Deficiency Syndrome (AIDS) medication protocols require the patient to consume two or more medications, but on alternating or sequential days. Although each medication is held in a separate container, the memory strip on each medication container could provide instructions on taking both medications. (COL. 3, LN. 64 to COL. 4, LN. 6)

Clearly, the Examiner has mischaracterized the teaching of the Huerga reference. Clearly, Huerga does not teach "wirelessly communicating a signal between the first container and a second container." At most, Huerga teaches transmitting information from container caps "to a separate personal or business computer." However it is very clear from the above passages and the rest of the references that there is no communication between containers. Therefore, the relied upon references do not teach features recited in Applicants claims. Thus, for this reason alone, Applicants respectfully request that the Examiner withdraw the Section 103 rejection of Claims 2 to 47, 49, 50, 116 to 125.

Further, the only motivation that the Examiner provides to combine Reber and Huerga is that the combination would allow "communicating instructions for alternating between differing medications in a controlled sequence (de la Huerga; col.3, col.3, line 64-col. 4, line 6)." The Examiner has not established a *prima facie* case of obviousness in that a proper motivation to combine Reber and Huerga has not been provided. The Examiner's stated motivation is merely a desirable function (that might be able to be implemented by the Examiner's combination, but it is not clear how) that is already available in the system of Huerga implemented in a different way (communicating with a separate personal or business computer). In other words, one would not be motivated to make the Examiner's combination for the reason provided by the Examiner since Huerga is able to provide the function of alternating between differing medications in a controlled sequence without transmitting signals between containers. Thus, even if Huerga taught transmitting signals between containers, which it does not, the Examiner's rejection would still be untenable because a proper motivation to combine Reber and Huerga has not been provided. Thus, for this additional reason, Applicants respectfully request that the Examiner withdraw the Section 103 rejection of Claims 2 to 47, 49, 50, 116 to 125.

Further, regarding Claims 24, 39, 40, 122 to 124, Applicants do not accept nor agree with the Examiner's characterization of the features of the claims that stand rejected based upon Reber and Huerga in view of factual assertions Officially Noticed by the Examiner. In each

case, the officially-noted subject matter comprises the principal evidence upon which the rejection was based. In other words, the Examiner relies upon officially-noted subject matter to show that a feature of the rejected claim was in the prior art. For the record, Applicants dispute all of the various assertions in the Office Action (with regard to all the claims) regarding what is "old and well known" and/or otherwise officially-noted. Applicants likewise dispute all assertions which were not proper factual findings because they are mere unsupported conclusions.

Applicants respectfully remind the Examiner that officially-noted subject matter cannot be used as the primary basis for a rejection under 103. In other words, official notice alone of what existed in the prior art is not permitted. A reference must be provided to show the scope and content of the prior art. See, e.g., *In re Ahlert*, 424 F.2d 1088 (C.C.P.A. 1969) ("Assertions of technical facts in areas of esoteric technology **must always be supported by citation to some reference work** recognized as standard in the pertinent art and the appellant given, in the Patent Office, the opportunity to challenge the correctness of the assertion or the notoriety or repute of the cited reference. ... Allegations concerning specific 'knowledge' of the prior art, which might be peculiar to a particular art should also be supported and the appellant similarly given the opportunity to make a challenge.") (emphasis added); *In re Eynde*, 480 F.2d 1364 (C.C.P.A. 1973) ("[W]e reject the notion that judicial or administrative notice may be taken of the state of the art. Facts constituting the state of the art in a patent case are normally subject to the possibility of rational disagreement among reasonable men, and **are not amenable to the taking of judicial or administrative notice.**") (emphasis added); *In re Pardo*, 684 F.2d 912 (C.C.P.A. 1982) ("[T]his court will always **construe [the rule permitting judicial notice] narrowly** and will regard facts found in such manner with an eye toward narrowing the scope of any conclusions to be drawn therefrom. Assertions of technical facts in areas of esoteric technology **must always be supported by citation to some reference work** recognized as standard in the pertinent art and the appellant given, in the Patent Office, the opportunity to challenge the correctness of the assertion or the notoriety or repute of the cited reference.") (emphasis added) Official Notice may be used, if at all, to clarify the meaning of a reference. See, e.g., *In re Ahlert*, 424 F.2d 1088 (C.C.P.A. 1969) ("Typically, it is found necessary to take notice of facts which may be used to supplement or **clarify the teaching of a reference** disclosure, perhaps to justify or explain a particular inference to be drawn **from the reference** teaching.") (emphasis added).

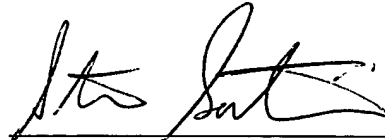
Accordingly, Applicants request a reference that describes the officially-noted subject matter in sufficient detail to provide Applicants an opportunity to determine its scope and an opportunity to distinguish the prior art from the present invention. MPEP 2144.03. Likewise, if the Examiner is relying upon his own personal knowledge of what was "old and well known," Applicants respectfully request that the Examiner provide an affidavit in support of his factual assertions. Short of such support for the Examiner's factual assertions, Applicants respectfully request withdrawal of the Section 103 rejection on this additional ground.

Conclusion

For the foregoing reasons it is submitted that all of the claims are in condition for allowance and the Examiner's early re-examination and reconsideration are respectfully requested.

Alternatively, if there remains any question regarding the present application or any of the cited references, or if the Examiner has any further suggestions for expediting allowance of the present application, the Examiner is cordially requested to contact Applicants' representative, Steven Santisi, at telephone number 203-461-7054 or via electronic mail at santisi@walkerdigital.com.

Respectfully submitted,



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Date

Steven Santisi
Registration No. 40,157
Attorney for Applicants
Walker Digital, LLC
santisi@walkerdigital.com
203-461-7054/ voice
203-461-7300/ fax